Chief Investigator	Prof Jonathan Green
Project ref number	Ref: 13/119/18
Project title	The Paediatric Autism Communication Trial - Generalised (PACT-G)

- Stop/Go decision points will form part of your contract with the Department of Health, and will be used by the EME Programme to review whether funding should continue at each identified stage of the project.

- Stop/Go decision points will be applied if there is a realistic expectation (other than failure to deliver) that a project could be discontinued at an appropriate stage.

- This table identifies the stages of the project and the criteria used in deciding whether the project should progress. The criteria should be robust and measurable. You will be expected to provide a report at stop/go points outlining whether the criteria have been met.

Stop/Go Decision Point 1 (S/G 1)
School buy-in

Time from start to S/G 1 (months)	12 months
Expenditure within S/G 1 (£)	£560,118
Estimate of meeting S/G 1 criteria (%)	40%

Milestones for S/G 1 (max 250 words, bulleted)
• At the end of the pilot phase of the trial, a minimum of 27 schools (9/site) will have been engaged with the school buy-in protocol. • Rationale: our sample have severe autism and at therefore least 50% will be in specialist autism schools with most of the others in specialist autism units within mainstream education (data from our previous PACT trial and its follow up study). Such schools and units are well known in our respective areas and can be further identified from organisations such as the National Autistic Society (http://www.autism.org.uk/directory). For instance in the North West site there are 4 specialist schools and up to 20 specialist units in mainstream schools; since placements will be skewed towards the specialist school environment, the majority of our participants are likely to be in a maximum of 18 schools in the area. We will thus be contacting about 50% of these within the pilot period – and the same will be true of the other sites. • The engagement protocol consists of; i) initial contact from senior therapists via the head teacher; ii) initial information pack explaining the study with telephone follow-up to discuss school-specific issues; iii) research team school visit with detailed presentation and Learning Support Assistant (LSA) orientation training; iv) written agreement from schools to take part in the study protocol in principle and/or specific agreement to take part with a recruited child.

Success criteria and target values (max 250 words, bulleted)
• Completion of engagement protocol and written confirmation of agreement to participate from 11/27 (>40%) of the schools approached during the pilot phase. • Rationale: Our agreed deliverability criteria states that, to achieve the recruitment target, less than 15% of the population pool need to be recruited and randomised. Assuming a worst-case scenario of the loss of 60% of patients approached due to lack of school buy-in, we would therefore still only require just 38% of the available patient pool to be recruited in order to achieve our recruitment target - a figure we consider still very achievable and that was exceeded in our PACT trial. Thus we set our minimum necessary criteria for progression at 40% school buy-in.

Reports required during S/G 1	Report of the procedure of contacting engaging schools, the outcome of the engagement and record of agreement letters received

Stop/Go Decision Point 2 (S/G 2)
Progression from identification to treatment

Time from start to S/G 2 (months)	12 months
Expenditure within S/G 2 (£)	£560,118
Estimate of meeting S/G 2 criteria (%)	25%

Milestones for S/G 2 (max 250 words, bulleted)
• By the end of the six-month external pilot phase (month 12 of the study) we will have identified, assessed for eligibility and consented sufficient cases for us to proceed to treatment in 24 cases (eight in each site).

Success criteria and target values (max 250 words, bulleted)
• Criteria for success is that <75% of identified and eligible patients are lost between identification and treatment initiation for reasons unrelated to school buy-in (itself addressed in SG1); or that a maximum of 96 cases have needed to be ascertained to achieve the pilot cohort of N=24. • Rationale: Our agreed deliverability criteria were that, to achieve the recruitment target, less than 15% of the available population pool need to be recruited and randomised. In our previous PACT trial,[6] which had the same recruitment protocol, 90/242 (37%) of cases identified as eligible were excluded before randomisation; and none lost between randomisation and treatment initiation. These exclusions before randomisation mainly related to non-consent, but also included moving out of area, loss of contact and other reasons. This trial over-recruited against target. We have no reason to consider that the exclusion rate would be higher in this current trial, but assume for the purpose of a worst-case scenario that 75% of

cases are lost between identification and randomisation. Even in this event recruitment to target would remain feasible since we would still need to identify then only 60% of the available patient pool. For the pilot phase we thus set minimum necessary threshold of 25% of ascertained cases progressing through to treatment. Since we achieved 63% to randomisation in the PACT trial, this is very achievable.

Reports required during S/G 2	Report identifying for the pilot phase: i) number of cases identified and ascertained as eligible; ii) number of cases proceeding through to treatment initiation.